REMARKS

This Amendment is made to the final Office Action dated June 6, 2008. Claims 1, 2, 4, 7-10 and 12-23 are currently pending. Claim 11 was previously withdrawn in response to an election of species requirement. By this Amendment, new claims 24-26 are being presented. Applicants respectfully request reconsideration of the pending claims in view of the remarks presented below.

The Examiner has objected to the previous amendments to the specification based on the belief that the amendment includes new matter. The Examiner believes that the following statements are not supported in the original disclosure:

> The torque handle 262 is directly mounted to the guide wire 28 and can be locked onto the guide wire via the cap 264. This handle 262 allows the physician to manipulate and rotate the guide wire 28. The torque device 280 includes an extension arm 284 having ....

However, Applicants believe that these statements are fully supported by the original specification as is disclosed in paragraph 52 and the drawings. The disclosure states the following in paragraph 52:

> This torque device 260 can be attached to a guide wire 280 and utilized by the physician to steer the embolic filtering system and guide wire within the patient's vasculature. The torque device 260 includes a handle 262 and a cap 264 which is utilized to squeeze the guide wire 280 via a collet within a lumen (not shown) that extends through the torque handle 260.

The particular torque device 260 disclosed in the specification is shown utilizing a conventional torque handle with cap, a commercially available medical device, that has been modified to include additional elements which creates a novel design. In this regard, as is disclosed in the specification and drawings, the handle 262 is mounted directly onto the guide wire 280 and the cap 264 is tightened (via the threads shown on the handle portion in the drawings) to squeeze the collet within the lumen through which

the guide wire extends to effectively lock the torque device 260 and handle 262 directly onto the guide wire 280. One skilled in the art would readily understand this disclosure based on the specification and drawings. Accordingly, no new matter has been added to the specification. Applicants respectfully request the Examiner to withdraw this rejection.

The Examiner has further rejected claims 1, 2, 4, 7-10, 12-14 and 18 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Examiner believes that the amendments to these claims to include a locking means is not supported in the written description. Again, as pointed out above, the torque device is shown and described as a conventional torque device which has been modified to include elements which create a novel design. The locking element is fully disclosed in the specification, as is addressed above, and its construction would be well recognized by one skilled in the art. Applicants submit that the claimed invention is fully supported in the specification and drawings. Applicants respectfully request the Examiner to withdraw this § 112, first paragraph rejection.

Claims 8-10 and 12-14 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,801,294 to Okada et al. (the "Okada patent"). Applicants strongly disagree with the Examiner's position that the Okada patent shows a torque device used to rotate or "torque" a guide wire to steer it through, for example, the vasculature of a patient. The Okada patent is merely directed to a fixture, referred to as a "fixing means B," which is used to split a plastic sheath tube 3a and 3b from a "very soft catheter body 1" (see Column 2, line 54 of the Okada patent). This very soft catheter body 1 is not a guide wire as the term "guide wire" is known and used in the medical field. For this reason alone, the Okada patent fails to disclose the device recited in the claims at issue.

Moreover, to the extent that the Examiner claims that the Okada device could alternatively be used to lock a guide wire in place, Applicants strongly disagree with the Examiner's position. First, the small hole 5' shown in the Okada device is utilized to

pinch or squeeze this very soft catheter body 1 to hold it in place. Hence, the catheter body 1 must be capable of deforming in order to be held in place. The Examiner is directed to Figure 2 and 3 of the Okada device which shows the catheter body 1 initially inserted into the larger hole 5 which has substantially the same diameter as the catheter body 1. In order for the Okada device to work, the catheter body 1 must deform to the smaller diameter size of hole 5'. Applicants respectfully submit that a guide wire will not so deform to be effectively pinched by the Okada device.

Additionally, the Okada device is not even used to rotate the catheter body 1 in any manner. The Okada patent states the following at Column 2, line 66 to Column 3, line 1:

> **After** the insertion of the tube A for nasogastric intubation having the catheter body 1 introduced therein, the **tube A is fixed to a fixing means B** externally of the nostril. (emphasis added)

Accordingly, the Okada patent fails to disclose the use of this "fixing means B" as a torquing device since tube A (catheter body 1 and sheath tube 3) is only fixed to the fixing means B after tube A has been inserted for nasogastric intubation.

This very soft catheter body 1 cannot be reasonably construed as a conventional guide wire and the Okada device would not be capable of deforming the guide wire as it does to the catheter body 1. Applicants respectfully request the Examiner to withdraw the Okada patent as an anticipatory reference.

Claims 1-4, 7 and 15-23 were rejected under 35 U.S.C. § 103 as being unpatentable over FPD FR 2580504 to Pieronne (the "Pieronne reference") in view of the Okada patent and in further view of U.S. Patent No. 6,616,680 to Thielen (the "Thielen patent"). Applicants strongly disagree with the Examiner's position. Claim 1 requires the filter assembly to include a self-expanding frame movable between an unexpanded position and an expanded position. The filter assembly disclosed in the Pieronne reference appears to use an inflatable balloon 8 to expand the filter. Thus, it lacks the self-expanding frame

recited in claim 1. Additionally, claims 1 and 15 recite that the torque device is directly mountable to the guide wire. In the Pieronne reference, the guide wire is designated with the reference numeral 27. A tubular catheter 15 is shown disposed over the guide wire 27. A splittable sheath 16 is, in turn, mounted over this tubular catheter member 15. Even assuming *arguendo* that the Okada patent discloses a torque device, the placement of the "fixing means B" of the Okada device on the Pieronne device would simply result in the Okada device being placed over the tubular catheter 15, not the guide wire 27. In this combination, the Okada device would be capable of pinching this flexible tubular catheter 15, as it designed to do, to hold the catheter 15 in place as the sheath 16 is being removed from the catheter 15. However, this tubular catheter 15 is not a guide wire as the guide wire is clearly disclosed as element 27. The Thielen patent fails to disclose the shortcomings of the Pieronne reference and the Okada patent. For at least these reasons, the combination of the Pieronne reference with the Okada and Thielen patents would not create the structure recited in the claims at issue. Applicants respectfully request the Examiner to withdraw the obviousness rejections of claims 1-4, 7 and 15-23.

Newly presented claims 24-26 are directed to the specific use of a collet to lock the guide wire in place. None of the art of record discloses the particular structure recited in these new claims.

Applicants remind the Examiner that a supplementary IDS was filed on September 4, 2007. The Examiner has not acknowledged submission of this IDS.

In view of the foregoing, it is respectively urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Please charge any fees payable in connection with this response to Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

By: /Thomas H. Majcher/
Thomas H. Majcher
Registration No. 31,119

THM:lm

304988.1